



INFORMATION DISCLOSURE STATEMENT BY APPLICANT PTO FORM 1449 Page 1/8	ATTY. DOCKET NO. 11220/128	SERIAL NO. 09/842,111
	APPLICANTS Kathleen D. DANENBERG	
	FILING DATE April 26, 2001	GROUP 1637

U. S. PATENT DOCUMENTS

EXAMINER INITIAL	PATENT/PUBLICATION NUMBER	PATENT DATE	NAME	CLASS	SUBCLASS	FILING DATE
✓	4,830,969	May 16, 1989	Holmes	435	259	
	4,843,155	Jun. 27, 1989	Chomczynski	536	27	
	5,128,247	Jul. 7, 1992	Koller	435	91	
	5,284,940	Feb. 8, 1994	Lin et al.	536	25.4	
	5,346,994	Sep. 13, 1994	Chomczynski	530	419	
	5,502,166	Mar. 26, 1996	Mishina	530	350	
	5,620,852	Apr. 15, 1997	Lin et al.	435	6	
	5,637,687	Jun. 10, 1997	Wiggins	536	25.4	
	5,643,767	Jul. 1, 1997	Fischetti et al.	435	91.3	
	5,654,179	Aug. 5, 1997	Lin	435	91.2	
	5,672,696	Sep. 30, 1997	Wang et al.	536	25.42	
	5,707,802	Jan. 13, 1998	Sandhu et al.	435	6	
	5,728,822	Mar. 17, 1998	Macfarlane	536	25.41	
	5,777,099	Jul. 7, 1998	Mehra	536	25.42	
	5,945,515	Aug. 31, 1999	Chomczynski	530	412	
	5,989,857	Nov. 23, 1999	Mundschenk	435	69.1	
✓	6,010,700	Jan. 4, 2000	Richt	424	186.1	
2	6,043,354	Mar. 28, 2000	Hillebrand et al.	536	25.42	



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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
2	WO 95/28489 A	Oct. 26, 1995	PCT/US				
	WO 97/05248	Feb. 13, 1997	PCT/US				
	WO 97/35034	Sept. 25, 1997	PCT/US				
2	WO 98/41648	Sept. 24, 1998	PCT/US				

OTHER DOCUMENTS

EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
2	Ardalan, B., et al., "Thymidylate Synthase Gene Expression in Normal and Malignant Colorectal Tissues: Relation to in vivo Response and Survival," Proceedings of the American Association for Cancer Research, Vol. 37, Abstract No. 1376 (March 1996).
	Ausubel, F.M., ed., <u>Current Protocols In Molecular Biology</u> , John Wiley & Sons, Inc., Vol. 1.; Strauss, W. M., "Preparation of Genomic DNA from Mammalian Tissue," Unit 2.2, pp. 2.2.1-2.2.3 (1998)
	Ausubel, F.M., ed., <u>Current Protocols In Molecular Biology</u> , John Wiley & Sons, Inc., Vol. 1.; Richards, E., et al., "Preparation of Genomic DNA from Plant Tissue," Unit 2.3, pp. 2.3.1-2.3.7 (1994)
	Ausubel, F.M., ed., <u>Current Protocols In Molecular Biology</u> , John Wiley & Sons, Inc., Vol. 1.; Wilson, K., "Preparation of Genomic DNA from Bacteria," Unit 2.4, pp. 2.4.1-2.4.5 (1994)
	Banerjee, S.K., et al, "Microwave-Based DNA Extraction from Paraffin-Embedded Tissue for PCR Amplification," BioTechniques, Vol. 18, No. 5, pp. 768, 770, 772, 773 (1995).
2	Benhattar, J., et al., "p53 Mutations as a Possible Predictor of Response to Chemotherapy in Metastatic Colorectal Carcinomas," Int. J. Cancer (Pred. Oncol.), Vol. 69, pp. 190-192 (1996).











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EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
	Bresters, D., et al., "Detection of Hepatitis C Viral RNA Sequences in Fresh and Paraffin-Embedded Liver Biopsy Specimens of Non-A, Non-B Hepatitis Patients," J. Hepat., Vol. 15, pp. 391-395 (1992).
	Bresters, D., et al., "The Duration of Fixation Influences the Yield of HCV cDNA-PCR Products from Formalin-Fixed, Paraffin-Embedded Liver Tissue," J. Virol. Method, Vol. 48, pp. 267-272 (1994).
	Chirgwin, J., M., et al., "Isolation of Biologically Active Ribonucleic Acid from Sources Enriched in Ribonuclease," Biochemistry, Vol. 18, No. 24, pp. 5294-99 (1979).
	Chomczynski, P., et al., "Single-Step Method of RNA Isolation by Acid Guanidinium Thiocyanate-Phenol-Chloroform Extraction," Analytical Biochemistry, Vol. 162, pp. 156-159 (1987).
	Chomczynski, P., "A Reagent for the Single-Step Simultaneous Isolation of RNA, DNA and Proteins from Cell and Tissue Samples," BioTechniques, Vol. 15, No. 3, pp. 532-4, 536-7 (1993).
	Coombs, N. J., et al., "Optimisation of DNA and RNA Extraction from Archival Formalin-Fixed Tissue," Nucl. Acids Research, Vol. 27, No. 16, pp. i-iii (1999).
	Dakhama, A., et al., "Amplification of Human β -Actin Gene by the Reverse Transcriptase-Polymerase Chain Reaction: Implications for Assessment of RNA from Formalin-Fixed, Paraffin-Embedded Material," J. Histochem. and Cytochem., Vol. 44, No. 10, pp. 1205-1207 (1996).
	de Andr�s, B., et al., "Improved Method for mRNA Extraction from Paraffin-Embedded Tissues," BioTechniques, Vol. 18, No. 1, pp. 42-43 (1995).
	Eads, C. A., et al., "CpG Island Hypermethylation in Human Colorectal Tumors is Not Associated with DNA Methyltransferase Overexpression," Cancer Research, Vol. 59, pp. 2302-2306 (1999).
	Edamoto, Y., et al., "Hepatitis C and B Virus Infections in Hepatocellular Carcinoma," CANCER, Vol. 77, No. 9, pp. 1787-1791 (1996).



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EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
	Farrugia, D., et al., "A pharmacodynamic (PD) study of the thymidylate, synthase (TS) Inhibitor Tomudex™ in advanced colorectal cancer (CRC)," Proceedings of the American Association for Cancer Research, Eighty-eighth Annual Meeting (April 12-16, 1997), Vol. 38 (1997), Abstract #4132.
	Finke, J., et al., "An Improved Strategy and a Useful Housekeeping Gene for RNA Analysis from Formalin-Fixed, Paraffin-Embedded Tissues by PCR," BioTechniques, Vol. 14, No. 3, pp. 448-53 (1993).
	Goldsworthy, S. M., et al., "Effects of Fixation on RNA Extraction and Amplification from Laser Capture Microdissected Tissue," Molecular Carcinogenesis, Vol. 25, pp. 86-91 (1999).
	Greer, C. E., et al., "PCR Amplification from Paraffin-Embedded Tissues," Am. J. Clin. Pathol., Vol. No. 95, No. 2, pp. 117-24 (1991).
	Gruber, A. D., et al., "Detection of Bovine Viral Diarrhea Virus RNA in Formalin-Fixed, Paraffin-Embedded Brain Tissue by Nested Polymerase Chain Reaction," J. Virol. Methods, Vol. 43, pp. 309-319 (1993).
	Guerrero, R.B., et al., "Effects of Formalin Fixation and Prolonged Block Storage on Detection of Hepatitis C Virus RNA in Liver Tissue," Diag. Molec. Path., Vol. 6, No. 5, pp. 277-281 (1997).
	Hodges, E., et al., "Isolation of Nucleic Acid from Paraffin Embedded Tissue for PCR Amplification and Sequencing of TcR Vβ Genes," Leuk. Research, Vol. 19, No. 3, pp. 183-186 (1995).
	Horie, N., et al., "Functional Analysis and DNA Polymorphism of the Tandemly Repeated Sequences in the 5' terminal Regulatory Region of the Human Gene for Thymidylate Synthase," Cell Structure and Function, Vol. 20, No. 3, pp. 191-197 (1995).
	Horikoshi, T., et al., "Quantitation of Thymidylate Synthase, Dihydrofolate Reductase, and DT-Diaphorase Gene Expression in Human Tumors using the Polymerase Chain Reaction," Cancer Res., Vol. 52, pp. 108-116 (1992).



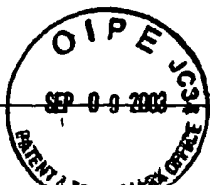
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✓	Hsuih, T. C. H., <i>et al.</i> , "Novel, Ligation-Dependent PCR Assay for Detection of Hepatitis C Virus in Serum," J. Clin. Microbiol., Vol. 34, No. 3, pp. 501-507 (1996).
	Iwamoto, K. S., <i>et al.</i> , "Feasibility of Using Decades-Old Archival Tissues in Molecular Oncology/Epidmiology," Am. J. Path., Vol. 149, No. 2, pp. 399-406 (1996).
	Jackman, A. L., <i>et al.</i> , "Thymidylate Synthetase Inhibitors: Experimental and Clinical Aspects," Chapter 7 in Experimental and Clinical Progress in Cancer Chemotherapy, F.M. Muggia, ed., Martinus Nijhoff, Boston (1985), pp. 155-210.
	Jiang, Y.-H., <i>et al.</i> , "A Rapid RT-PCR Method for Detection of Intact RNA in Formalin-Fixed Paraffin-Embedded Tissues," Nucl. Acids. Res., Vol. 23, No. 15, pp. 3071-2 (1995).
	Kawakami, K., <i>et al.</i> , "Polymorphic Tandem Repeats in the Thymidylate Synthase Gene is Associated with its Protein Expression in Human Gastrointestinal Cancers," Proceedings of the American Society of Clinical Oncology, Vol. 17, Abstract No. 1128 (May 1998).
	Keyomarsi, K., <i>et al.</i> , "Mechanism of the Cytotoxic Synergism of Fluoropyrimidines and Folinic Acid in Mouse Leukemic Cells," J. Biol. Chem., Vol. 263, No. 28, pp. 14402-14409 (1988).
	Kiyosawa, K., <i>et al.</i> , "Interrelationship of Blood Transfusion, Non-A, Non-B Hepatitis and Hepatocellular Carcinoma: Analysis by Detection of Antibody to Hepatitis C Virus," Hepatology, Vol. 12, No. 4, pp. 671-5 (1990).
✓	Koopmans, M., <i>et al.</i> , "Optimization of Extraction and PCR Amplification of RNA Extracts from Paraffin-Embedded Tissue in Different Fixatives," J. Virological Methods, Vol. 43, pp. 189-204 (1993).
~	Lenz, H.-J., <i>et al.</i> , "p53 and Thymidylate Synthase Expression in Untreated Stage II Colon Cancer: Associations with Recurrence, Survival, and Site," Clinical Cancer Research, Vol. 4, pp. 1227-34 (1998).



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N	Lenz, H.-J., <i>et al.</i> , "Thymidylate Synthase mRNA Level in Adenocarcinoma of the Stomach: A Predictor for Primary Tumor Response and Overall Survival," J. Clinical Oncology, Vol. 14, No. 1, pp. 176-182 (1996).
	Macfarlane, D. E., <i>et al.</i> , "Introduction to Isolating RNA," in RNA Isolation and Characterization Protocols, R. Rapley and D. L. Manning, eds., Humana Press (Series: Methods in Molecular Biology™), Totowa, N. J. (1998), pp. 1-6.
	Marsh, S., <i>et al.</i> , "Ethnic Variation in the Thymidylate Synthase Enhancer Region Polymorphism among Caucasian and Asian Populations," Genomics, Vol. 58, pp. 310-312 (1999).
	Mies, C., "A Simple, Rapid Method for Isolating RNA from Paraffin-embedded Tissues for Reverse Transcription-Polymerase Chain Reaction (RT-PCR)," J. Histochemistry and Cytochemistry, Vol. 42, No. 6, pp. 811-813 (1994).
	Miyauchi I., <i>et al.</i> , "Further study of hepatitis C virus RNA detection in formalin-fixed, paraffin-embedded liver tissues by ligation-dependent polymerase chain reaction", Pathology International, Vol. 48, pp. 428-432 (1998)
	Mizuno, T., <i>et al.</i> , "RNA from Decades-Old Archival Tissue Blocks for Retrospective Studies," Diagnostic Molecular Pathology, Vol. 7, No. 4, pp. 202-208 (1998).
	Mukhopadhyay, T., <i>et al.</i> , "Isolation of Total RNA from Tissues or Cell Lines," in RNA Isolation and Characterization Protocols, R. Rapley and D. L. Manning, eds., Humana Press (Series: Methods in Molecular Biology™), Totowa, N.J. (1998), pp. 55-59.
✓	Park, Y. N., <i>et al.</i> , "Detection of Hepatitis C Virus RNA Using Ligation-Dependent Polymerase Chain Reaction in Formalin-Fixed, Paraffin-Embedded Liver Tissues," American Journal of Pathology, Vol. 149, No. 5, pp. 1485-1491 (1996).
N	Rupp, G. M., <i>et al.</i> , "Purification and Analysis of RNA from Paraffin-Embedded Tissues," BioTechniques, Vol. 6, No. 1, pp. 56-60 (1988).



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EXAMINER INITIAL	AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.
	Sambrook, J., <i>et al.</i> , "Isolation of High-Molecular-Weight DNA from Mammalian Cells," in Molecular Cloning: A Laboratory Manual, 2 nd Ed., Cold Spring Harbor Laboratory Press (1989), pp. 9.14-9.23.
	Sander, C. A., <i>et al.</i> , "p53 Mutation is Associated with Progression in Follicular Lymphomas," Blood, Vol. 82, No. 7, pp. 1994-2004 (1993).
	Santos, A. C., <i>et al.</i> , "Simultaneous Extraction of RNA and DNA from Paraffin-Embedded Tissues," Trends in Genetics, Vol. 9, No. 7, p. 231 (1993).
	Soguero, C., <i>et al.</i> , "Detection of Hepatitis C Virus RNA in More Than 20-Year Old Paraffin-Embedded Liver Tissue," Laboratory Investigation, Vol. 79, No. 3, pp. 365-366 (1999).
	Sorg, I., <i>et al.</i> , "Detection of Borna Disease Virus RNA in Formalin-Fixed, Paraffin-Embedded Brain Tissues by Nested PCR," J. Clinical Microbiology, Vol. 33, No. 4, pp. 821-823 (1995).
	Spears, C. P., <i>et al.</i> , "In Vivo Kinetics of Thymidylate Synthetase Inhibition in 5-Fluorouracil-Sensitive and -Resistant Murine Colon Adenocarcinomas," Cancer Research, Vol. 42, pp. 450-456 (1982).
	Stanta, G., <i>et al.</i> , "RNA Extracted from Paraffin-Embedded Human Tissues is Amenable to Analysis by PCR Amplification," BioTechniques, Vol. 11, No. 3, pp. 304-308 (3 pages) (1991).
	Swain, S. M., <i>et al.</i> , "Fluorouracil and High-Dose Leucovorin in Previously Treated Patients with Metastatic Breast Cancer," J. Clinical Oncology, Vol. 7, No. 7, pp. 890-899 (1989).
	Wei, X., <i>et al.</i> , "Molecular Basis of the Human Dihydropyrimidine Dehydrogenase Deficiency and 5-Fluorouracil Toxicity," J. Clinical Investigation, Vol. 98, No. 3, pp. 610-615 (1996).



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<i>[Signature]</i>	v. Weizsäcker, F., et al., "A Simple and Rapid Method for the Detection of RNA in Formalin-Fixed, Paraffin-Embedded Tissues by PCR Amplification," <i>Biochem. and Biophys. Research Comm.</i> , Vol. 174, No. 1, pp. 176-180 (1991).

EXAMINER <i>[Signature]</i>	DATE CONSIDERED <i>6/30/01</i>
EXAMINER: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	